IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v. CIVIL ACTION NO. 2:24-cv-00271

PATRICK MORRISEY,
in his official capacity as Attorney General of West Virginia, et al.,

Defendants.

* * * * *

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v. CIVIL ACTION NO. 2:24-cv-00272

PATRICK MORRISEY,
in his official capacity as Attorney General of the State of West Virginia, et al.,

Defendants.

* * * * *

ABBVIE INC. et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:24-cv-00298

PATRICK MORRISEY
in his official capacity as the West Virginia Attorney General, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the Court are several motions. The first three are motions by Pharmaceutical Research and Manufactures of America, Inc. ("PhRMA"), Novartis Pharmaceuticals Corporation ("Novartis"), and AbbVie Inc. ("AbbVie") (collectively "Plaintiffs"). Plaintiffs have each moved for a preliminary injunction under Federal Rule of Civil Procedure 65. (Case No. 2:24-cv-00271, ECF No. 20); (Case No. 2:24-cv-00272, ECF No. 6); (Case No. 2:24-cv-00298, ECF No. 7). In response to PhRMA's motion, defendants—which include West Virginia Attorney General Patrick Morrisey among other West Virginia officials (collectively "Defendants")—moved to dismiss PhRMA's case because "PhRMA lacks associational standing to assert the claims and claims for relief that it brings in this action." (Case No. 2:24-cv-00271, ECF No. 34.) For the reasons discussed below, Plaintiffs' motions are **GRANTED** and Defendants' motion is **DENIED**.

I. BACKGROUND

A. The 340B Program

In 1992, Congress enacted the Veterans Health Care Act ("the Act"). (Case No. 2:24-cv-

00272, ECF No. 28 at 8.) Part of the Act included a bargain with drug manufacturers: in exchange for being reimbursed under the Medicare Part B and Medicaid programs, drug manufacturers were required to offer discounts to "covered entities." (*Id.*) These covered entities, defined now by 42 U.S.C. § 256b(a)(4), would receive a discount based on a formula outlined in § 256b(a)(2) of the Act. (*See* Case No. 2:24-cv-00272, ECF No. 28 at 8.) Known as the "340B Program,"[1] this scheme was a part of Congress's larger goal of combating rising drug costs on state funded Medicaid programs. (*Id.*) As required by the 340B Program, a manufacturer "shall . . . offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). This pricing scheme enables covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (Case No. 2:24-cv-00272, ECF No. 28 at 9 (citing H.R. Rep. No. 102-384, pt. 2, at 12).)

The covered entities of the 340B Program are not low-income patients themselves. Nor are they pharmacies *per se*. Instead "covered entities" are largely "local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 115 (2011); *see also* 42 U.S.C. § 256b(a)(4)(A)–(O). The requirement that covered entities be offered a discounted price via the 340B Program is reflected in a contract that runs between drug manufacturers and the Department of Health and Human Services ("HHS"), the 340B Program administrator. *See Astra*, 563 U.S. at 113. These form contracts do not include covered entities as parties to the contract. Rather, the covered entities are merely third-party beneficiaries that

[1] The term "340B" derives from Section 340B of the Public Health Service Act, which was originally passed in 1944. The use of 340B as a shorthand to describe drug price reduction for covered entities became popularized following the term's usage throughout the Veterans Health Care Act of 1992. *See generally* 106 Stat. 4962–71 (1992).

have little to no enforcement power. *See id.*

As part of the 340B Program, Congress required HHS to create program enforcement rules. Specifically, Congress required HHS to "promulgate regulations to establish and implement an administrative process for the resolution of claims." 42 U.S.C. § 256b(d)(3)A). This dispute resolution program is meant to resolve two types of claims. First, covered entities may seek resolution when they believe "they have been overcharged for drugs purchased under [the 340B Program]." *Id.* Second, Congress required a program that allows for "claims by manufacturers . . . of violations of subsections (a)(5)(A) or (a)(5)(B)" of the Act. *Id.* Before a manufacturer may raise such a claim, Congress requires that manufacturers first "conduct . . . audits as authorized by subsection (a)(5)(C)" of the Act. *Id.*

As for the 340B audit provision, Congress vested authority to conduct audits in both HHS and manufacturers. The 340B Program states that "[a] covered entity shall permit [HHS and a manufacturer] . . . to audit . . . the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer." 42 U.S.C. § 256b(a)(5)(C). These audits enable the manufacturers to verify compliance with the prohibition on duplicate discounts, such as prescriptions already discounted by Medicare, and for prohibiting the resale of program discounted drugs. *See* 42 U.S.C. § 256b(a)(5)(A)–(B). As such, HHS promulgated regulations under 42 C.F.R. § 10.21 (2024). Like the Act itself, § 10.21 also requires an audit prior to starting a dispute resolution claim. *See* 42 C.F.R. § 10.21(a)(2) ("Claims by a manufacturer, after it has conducted an audit of a covered entity . . . .").

B. The "Replenishment Model"

Many of the 340B covered entities do not have their own in-house pharmacies. (Case No. 2:24-cv-00272, ECF No. 28 at 10.) Instead, covered entities rely on independent, retail pharmacies to serve their prescription filling needs. (*Id.*) These pharmacies are known as "contract pharmacies" who, although otherwise prohibited from purchasing drugs under the 340B Program, are permitted to do so through an arrangement with the covered entity. (*Id.* at 11.) Under this system, covered entities purchase and take title to the manufacturer's drugs, while contract pharmacies take physical possession. (*Id.*) This system, not unique to covered entities, appears to have existed as an unofficial operation of the 340B Program for years. (*See id.* at 11–12.)

The operating model for distributing drugs under the 340B Program is known as the "replenishment model." Under this model, a contract pharmacy sells its existing stockpile of drugs to patients. (*See* Case No. 2:24-cv-00272, ECF No. 7 at 14.) Only after both drug and patient have left the pharmacy does the covered entity designate the distributed drug as 340B Program eligible, making it available at the 340B price. (*See id.*) The contract pharmacy then replaces its distributed drug with a new one ordered by the covered entity at the 340B price. (*Id.*); *see also Novartis Pharmaceuticals Corp. v.* Johnson, 102 F.4th 452, 457 (D.C. Cir. 2024) ("Once the pharmacy or the administrator categorizes a certain number of prescriptions as eligible, the pharmacy places an order to replenish its section 340B purchases."). The contract pharmacy then "comingles the 340B-purchased unit with" those available to the general public, and "thus is available for dispensing to anyone, including a non-patient of the covered entity." (Case No. 2:24-cv-00272, ECF No. 7 at 14.) This model was not disputed by Defendants as the operative

system at the hearing on this preliminary injunction motion.[2] *See* Prelim. Inj. Hr'g Tr. (Case No. 2:24-cv-00272, ECF No. 53 at 72 ("The pharmacy goes ahead and fills it on the spot and submits the -- if the patient has insurance, if they have Medicare/Medicaid reimbursement. It passes that up the line and that process plays itself out so that the patient isn't burdened with the 340B mechanism.").)

C. West Virginia S.B. 325 and Procedural History

According to Defendants and Amici,[3] the utilization of contract pharmacies by covered entities remained undisturbed until July of 2020. (*See* Case No. 2:24-cv-00272, ECF No. 28 at 12); (Case No. 2:24-cv-00272, ECF No. 31 at 8–9.) Then, drug manufacturers, including Plaintiffs to this suit, began to restrict the arrangement by which contract pharmacies would obtain and distribute drugs through the 340B Program. (Case No. 2:24-cv-00272, ECF No. 28 at 12.) Drug manufacturers, including Plaintiffs, began to "either fully eliminate[] or significantly restrict[] distribution of 340B drugs ordered through bill to/ship to arrangements" between covered entities and contract pharmacies. (*Id.*) Plaintiffs allege this response stems from the concern that unrestricted use of contract pharmacies "greatly exacerbated longstanding systemic 340B Program integrity concerns, including the risk that 340B drugs are being diverted to non-patients [or] the subject of duplicate discounts." (Case No. 2:24-cv-00272, ECF No. 17 at 8.) According to Defendants, such restrictions "deprived covered entities of the revenue and savings that Congress

[2] The existence of the replenishment model seems supported by the supplemental authority filed by PhRMA (*See* Case No 2:24-cv-002721, ECF No. 66-1 at 6.) Although that authority cites a sample contract pharmacy agreement from Arizona, it shows how the replenishment model operates within the industry.

[3] Amici include: American Hospital Association, an organization that represents "nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide" through amicus advocacy; 340B Health, a "not-for-profit organization" that "represents over 1,500 public and private nonprofit hospitals and health systems participating in the 340B program"; and the West Virginia Hospital Association, "a not-for-profit statewide organization representing hospitals and health systems." (Case No 2:24-cv-00272, ECF No. 31 at 7.)

intended for the 340B Program." (Case No. 2:24-cv-00272, ECF No. 28 at 12.) These "restrictions," allege Amici, "have substantially cut the savings from the 340B program, which is devastating for the very hospitals in West Virginia that provide 86% of all hospital care that is provided to Medicaid patients." (Case No. 2:24-cv-00272, ECF No. 31 at 9–10.)

Responding to these new restrictions, the West Virginia legislature enacted S.B. 325—now codified as West Virginia Code § 60A-8-6a. (*See* Case No. 2:24-cv-00272, ECF No. 28 at 12.) In addition to definitions that largely cross-reference federal law, S.B. 325 has three interrelated features. First, the law states that drug manufacturers "shall not, either directly or indirectly, deny, restrict, or prohibit the acquisition of a 340B drug by, or delivery of a 340B drug to, a location authorized by a 340B entity to receive such 340B drug," unless otherwise prohibited by federal law. W. Va. Code § 60A-8-6a(b)(1) (hereinafter referred to as the "No-Restrictions Provision"). Second, the law restricts a drug manufacturer's ability to acquire claims and utilization data by stating that no manufacturer shall directly or indirectly "require a 340B entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless" the data is required to be shared by federal law. W. Va. Code § 60A-8-6a(b)(2) (hereinafter referred to as the "No-Audits Provision"). Finally, West Virginia enacted a penalties section to enforce the previous two provisions. That portion of S.B. 325 creates the following penalties and procedures for violations of either the No-Audits or No-Restrictions Provisions: a civil penalty of $50,000 per violation; investigatory power and civil suit authorization in the West Virginia Attorney General; enforcement under the general unfair trade practice laws of West Virginia; civil suit referral powers in the West Virginia Board of Pharmacy; rulemaking authority in the West Virginia Board of Pharmacy; and the ability to "discipline, or

suspend[], or revok[e] the license or permit of any [drug] manufacturer" who is found to be non-compliant. W. Va. Code § 60A-8-6a(c)(1)–(3) (hereinafter referred to as the "Enforcement Provisions"). The final portion of S.B. 325 added interpretive language in an attempt to avoid preemption under federal law. W. Va. Code § 60A-8-6a(d)

The Plaintiffs filed suit accordingly, seeking declaratory and injunctive relief.[4] (Case No. 2:24-cv-00271, ECF No. 1); (Case No. 2:24-cv-00272, ECF No. 1); (Case No. 2:24-cv-00298, ECF No. 1). Each of the Plaintiffs moved the Court under Federal Rules of Civil Procedure 65 to enjoin S.B. 325 pending a final disposition of this case on the merits. (Case No. 2:24-cv-00271, ECF No. 20); (Case No. 2:24-cv-00272, ECF No. 6); (Case No. 2:24-cv-00298, ECF No. 7). The cases continue to proceed separately as of the date of this order. However, for purposes of the preliminary injunction only, the parties have proceeded as if this were a single motion. Status Conference Hr'g Tr. for July 15, 2024 (Case No. 2:24-cv-00272, ECF No. 42 at 7–9, 14.) On September 16, 2024, the Court held a hearing where Plaintiffs and Defendants supplemented their written arguments. As such, all motions for preliminary injunctive relief are fully briefed and ripe for adjudication.

II. LEGAL STANDARD

"Rule 65 of the Federal Rules of Civil Procedure provides for the issuance of preliminary injunctions as a means of preventing harm to one or more of the parties before the court can fully adjudicate the claims in dispute." *Williams v. Rigg*, 458 F. Supp. 3d 468, 473 (S.D. W. Va. 2020). Preliminary injunctions are "never awarded as of right." *Id.* (citing *Real Truth About Obama, Inc.*

[4] AstraZeneca Pharmaceuticals LP ("AstraZeneca") filed a similar suit for relief in a related case. (*See* Case No. 2:24-cv-00290, ECF No. 1.) However, as indicated in the status conference held July 15, 2024, AstraZeneca did not move for a preliminary injunction. (Case No. 2:24-cv-00290, ECF No. 20.) Therefore, this order is inapplicable to AstraZeneca.

v. FEC, 575 F.3d 342 345 (4th Cir. 2009)). Rather, it is an "extraordinary remed[y] involving the exercise of very far-reaching power," and should only be granted "sparingly and in limited circumstances." *MicroStrategy, Inc. v. Motorola, Inc.*, 245 F.3d 335, 339 (4th Cir. 2001).

To succeed on a preliminary injunction, the Court must find that the movants have satisfied the four factors set by the Supreme Court in *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7 (2008). Those factors include: 1) that the movant "is likely to succeed on the merits"; 2) that the movant "is likely to suffer irreparable harm in the absence of preliminary relief"; 3) "that the balance of the equities tips in [the movant's] favor"; and 4) "that an injunction is in the public interest." *Vitkus v. Blinken*, 79 F.4th 352, 361 (4th Cir. 2023) (citing *Winter*, 555 U.S. at 20). "All four elements must be established by a 'clear showing' before the injunction will issue." *Imagine Medispa, LLC v. Transformations, Inc.*, 999 F. Supp. 2d 862, 868 (S.D. W. Va. 2014) (quoting *Real Truth About Obama*, 575 F.3d at 346). The plaintiff bears the burden of showing a "sufficient factual basis" for granting the injunction "beyond the unverified allegations in the pleadings." *Id.* at 868–69 (citations omitted).

III. DISCUSSION

The Court, being satisfied that it has jurisdiction,[5] will proceed to the merits of all

[5] Defendants raised a challenge to jurisdiction on both Fed. R. Civ. P. 12(b)(1) and 12(b)(6). (Case No. 2:24-cv-00271, ECF No. 34.) A Rule 12(b)(6) challenge to subject matter jurisdiction stems from the "[l]ess well-known . . . concept of statutory standing" and asks "whether the plaintiff is a member of the class given authority by a statute to bring suit." *CGM, LLC v. BellSouth Telecommunications, Inc.*, 664 F.3d 46, 52 (4th Cir. 2011). Nowhere do Defendants' memoranda of support indicate that PhRMA is not a member of a class who can seek remedies under the Declaratory Judgement Act, codified at 28 U.S.C. § 2201(a), or a preliminary injunction under Fed. R. Civ. P. 65. (*See* Case No. 2:24-cv-00271, ECF No. 33 at 6–17.) That PhRMA is such a member seems obvious given that other courts have considered similar litigation invoking the Declaratory Judgment Act by PhRMA, and no court has indicated that PhRMA is not a litigant who can seek such relief. *See, e.g.*, *Pharmaceutical Research and Manufacturers Association of America v. Fitch*, 2024 WL 3277365, *4 (S.D. Miss. July 1, 2024) (ruling on PhRMA's motion for preliminary injunction in case seeking to declare Mississippi law invalid through the Declaratory Judgment Act). Defendants fail to give any reason to conclude otherwise. Thus, the Court rejects Defendants' Rule 12(b)(6) challenge.

Plaintiffs' claims. Each of Plaintiffs' counsel presents a vast array of arguments to support the Court's decision to issue a preliminary injunction. The Court will not address every argument made. Instead, it will address all relevant arguments to the meritorious rationales for enjoining the law until final disposition. The Court will address each of the *Winter* factors below.

A. Factor One: Plaintiffs are Likely to Succeed on the Merits

i. The No-Audits Provision

As noted earlier in this opinion, the No-Audits Provision restricts a drug manufacturer from obtaining claims and utilization data from a covered entity as a condition for obtaining 340B Program drugs. Plaintiffs assert this creates an obstacle to utilizing 340B's federally based alternative dispute resolution system. PhRMA argues in its memorandum that "S.B. 325 cuts off" a drug manufacturer's ability "to gather information that will allow them to determine if reasonable cause exists to suspect a covered entity is violating 340B's provisions." (Case No. 2:24-cv-00271, ECF No. 21 at 31.) That is because, as PhRMA argues, an audit only becomes available to a manufacturer when they "ha[ve] documentation which indicates there is reasonable cause." (*Id.*) Indeed, federal law reflects PhRMA's assertion. *See* 61 Fed. Reg. 65406, 65409 (Dec. 12, 1996) ("A manufacturer shall conduct an audit only when it has documentation which indicates

Similarly, the Court rejects the challenge on a Rule 12(b)(1) argument regarding a lack of associational standing. An organization can meet the Article III standing either by claiming "it suffered an injury in its own right or, alternatively, it can assert 'standing solely as the representative of its members.'" *Students for Fair Admissions, Inc. v. President and Fellows of Harvard College*, 600 U.S. 181, 199 (2023) (citations omitted). This latter approach, "known as representational or organizational standing" can be met if "(a) [the organization's] members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.* First, PhRMA has shown that at least two of its members, Amgen and Gilead, would have standing to sue. (Case No. 2:24-cv-00271, ECF No. 47 at 13.) Second, among PhRMA's purposes is to represent its members "in litigation on behalf of its matters to ensure that members can continue to invest in research and development, including regarding 340B requirements and participation." (*Id.* at 15.) Finally, the participation in a suit for declaratory relief requires no individual participation of its members. (*Id.*) The Court agrees with PhRMA and rejects Defendants' Rule 12(b)(1) challenge to subject matter jurisdiction.

that there is reasonable cause."). As industry practice, drug manufacturers distribute 340B Program drugs to contract pharmacies based on the condition that claims data is shared with the manufacturer. (*See* Case No. 2:24-cv-00271, ECF No. 47 at 30–31.) These requirements have been characterized as a "minimal burden" by other courts and are widespread industry practice. (*See id.* at 30 (collecting cases).) Yet the No-Audits Provision "greatly hampers" this widespread practice and limits a manufacturer's ability to "gather information allowing them to determine if reasonable cause exists to suspect a covered entity is violating 340B." (*Id.*) Because S.B. 325 "create[s] a significant obstacle to the program's audit and ADR process," Plaintiffs argue the No-Audits Provision is conflict preempted. (Case No. 2:24-cv-00271, ECF No. 21 at 31.)

Defendants contend that such prohibitions on data collection do not stand as an obstacle to the federal program. They argue that S.B. 325 "does not prohibit manufacturers from obtaining information regarding the dispensing of 340B Drugs." (Case No. 2:24-cv-00271, ECF No. 33 at 16.) Instead, Defendants contend that the statute merely "prohibits manufacturers from imposing data sharing obligations as a condition to the receipt of a 340B Drug." (*Id.* at 17.) Ostensibly, this still leaves alternative channels to accessing data through "other lawful means." (*See id.*) ("[S.B. 325] does not prohibit manufacturers from requesting nor accessing dispensing data through other lawful means."). Defendants have not elaborated on what these alternative "lawful means" are.

Preemption analysis stems from the longstanding constitutional principle that state laws which impede federal law violate the Supremacy Clause. *See McCulloch v. Maryland*, 17 U.S. 316, 427 (1819). The Supremacy Clause of the United States Constitution requires that "the Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. "Any

state or local law conflicting with federal law is preempted and thus 'without effect.'" *Atlantic Coast Pipeline, LLC v. Nelson Co. Board of Supervisors*, 443 F. Supp. 3d 670, 678 (W.D. Va. 2020) (citing *Washington Gas Light Co. v. Prince George's County Council*, 711 F.3d 412, 419 (4th Cir. 2013)). There are effectively four circumstances in which state law is preempted by federal law. First is known as express preemption in which Congress "define[s] explicitly the extent to which its enactments pre-empt state law," making its intent to preempt state law "known through explicit statutory language." *English v. General Electric Co.*, 496 U.S. 72, 78–79 (1990). The second circumstance, derived by implying a Congressional intent to preempt, stems from the federal government's "occupying the field" of regulation in a manner "so pervasive . . . that Congress left no room for the States to supplement it," or when "there is a federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v. United* States, 567 U.S. 387, 400 (2012). The last two forms of preemption are distinct types of conflict preemption. The first variety of conflict preemption, known as "direct conflict," occurs when a state law stands as "a direct conflict between state and federal law, such that compliance with both is impossible." *College Loan Corp. v. SLM Corp.*, 396 F.3d 588, 596 (4th Cir. 2005) (citations omitted). The second, known as "obstacle preemption," applies when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373 (2000). Whichever form of conflict preemption the Court analyzes, it must take caution not to engage in a "freewheeling judicial inquiry into whether a state statute is in tension with federal objectives" since such an exercise "would undercut the principle that it is Congress rather than the courts that pre-empts state law." *Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582, 607

(2011) (citing *Gade v. National Solid Wastes Management Assn.*, 505 U.S. 88, 111 (1992)).

Most germane to the No-Audits Provision is obstacle preemption. What constitutes "a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby*, 530 U.S. at 373. "If the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power." *Id.* (citation omitted). Thus, the Court must identify the federal purpose of the 340B Program to analyze whether S.B. 325 creates an obstacle to federal law.

As other courts have put it, "[t]he purpose of [the 340B Program] is clear—it provides discounts on drugs to certain kinds of healthcare facilities." *Novartis Pharmaceuticals Corp. v. Espinosa*, 2021 WL 5161783, *7 (D. D.C. Nov. 5, 2021). As that court held, however, "no legislation pursues its purposes at all costs" and the 340B Program "is no exception." *See id.* (citing *CTS Corp. v. Waldburger*, 573 U.S. 1, 12 (2014)). Congress also fashioned the 340B Program to "prohibit[] covered entities from reselling or transferring discounted drugs to anyone who is not a patient of the covered entity" and, in order to "effectuate these anti-fraud provisions, the statute requires covered entities to allow audits by . . . the manufacturer" and subjects "covered entities to sanctions for noncompliance." *Id.* (citing 42 U.S.C. § 256b(a)(5)(A)–(D)). Thus, to fit comfortably within the federal law, a state law must not create an obstacle to twin federal purposes—providing discounts to covered entities only *and* prohibiting fraud through duplicate discounts.

The No-Audits Provision is an obstacle to both purposes. As indicated above, the 340B

Program authorizes a drug manufacturer to utilize the administrative dispute resolution system only "*after* the conduct of audits as authorized by" the statute. *See* 42 U.S.C. § 256b(d)(3)(A) (emphasis added); *see also* 42 C.F.R. § 10.21(a)(2) ("All [dispute] claims must be specific to the parties identified in the claims and are limited to . . . [c]laims by a manufacturer, *after* it has conducted an audit of a covered entity pursuant to [the statute]."") (emphasis added). Thus, conducting an audit serves as a condition precedent for a drug manufacturer to utilize the federal dispute resolution system, and S.B. 325 clearly restricts such a condition from being met. By restricting the very method by which data collection is made, S.B. 325 frustrates drug manufacturers' ability to take the initial steps necessary to start the very audit required to access the alternative dispute resolution system.

Although alternative "lawful means" are asserted to be available to Plaintiffs, Defendants have not substantively elaborated on what those means are. (*See* Case No. 2:24-cv-00271, ECF No. 47 at 30–31) ("The State offers no real answer to this clear and irreconcilable conflict. Instead, it merely asserts that 'SB 325 prohibits manufacturers from imposing data sharing obligations as a condition to the receipt of a 340B Drug, but it does not prohibit manufacturers from requesting nor accessing dispensing data through other lawful means.' . . . What other lawful means? The State's argument is a non sequitur."). One of the means offered by Defendants is that the drug manufacturers can "request" the data from the covered entities. (Case No. 2:24-cv-00271, ECF No. 33 at 17.) What then happens if a covered entity declines such a request? Defendants offer no alternatives. In fact, given that the No-Audits Provision forbids manufacturers from "indirectly[] require[ing] a 340B entity to submit claims utilization data," *see* W. Va. Code § 60A-8-6a(b)(2), it seems there is not much recourse available to a manufacturer.

Instead, covered entities—who may be engaging in the kind of fraud that the 340B Program's alternative dispute resolution system is meant to prevent—will essentially be the ones determining whether or not they wish to give manufacturers the very data necessary to start such an audit. The 340B Program certainly did not establish a system where the fox guards the hen house. By restricting a practice that the industry utilizes in order to take the first step toward accessing the 340B Program dispute resolution system, S.B. 325 creates an impermissible obstacle to executing the federal program.

Defendants offer no other meaningful alternative "lawful means" to get this data. Indeed, there appears to be none. The Defendants argued at the hearing on this motion that if the Court looks to "the manufacturer's audit process and the ADR process there is nothing about the claims data that they say that they want or need to be able to do that that they can't get through the federal process." Prelim. Inj. Hr'g Tr. (Case No. 2:24-cv-00272, ECF No. 53). Such an argument is circular—for it is this very data that is necessary to justify the audit in the first place.

In short, the No-Audits Provision hampers the ability of drug manufacturers to formulate the "reasonable cause" necessary to conduct an audit in the first place. Without an audit, Plaintiffs have no ability to access the federally administered alternative dispute resolution system set up by the 340B Program. As such, the No-Audits Provision goes well beyond simple tension with the federal objectives. Instead, it stands as an obstacle to achieving the federal objective of preventing fraud in the 340B Program. The Court accordingly **FINDS** that the Plaintiffs have met their burden to demonstrate likely success on the merits in challenging the No-Audits Provision.

ii. The Enforcement Provisions

With the No-Audits Provision likely preempted, the Court turns next to the Enforcement Provisions. Plaintiffs take issue with the state's chosen mechanism to enforce S.B. 325. As Novartis argued in its brief, the Enforcement Provisions create yet another "substantial obstacle" to achieving a federal purpose. (Case No. 2:24-cv-00272, ECF No. 7 at 27.) This purpose, Novartis says, stems from Congress placing "centralized enforcement" of the 340B Program "in the [federal] government" and creating a "unitary administrative and enforcement scheme" in order to harmoniously "administer both Medicaid and § 340B." (*Id.* (citing *Astra*, 563 U.S. at 119-20).) S.B. 325 creates a series of obstacles because it "deputizes the State Attorney General's office and Board of Pharmacy to impose civil penalties" under West Virginia law, adds additional fines "up to [$50,000] per violation," and imposes "criminal liability [on] any manufacturer that violates the state law." (*Id.*)

Within all of these enforcement mechanisms, Novartis argues that these same state actors would be called upon to determine questions of federal law. (Case No. 2:24-cv-00272, ECF No. 45 at 14.) As way of example, Novartis turns to a potential claim of diversion. (*Id.*) Suppose, as Novartis says, a drug manufacturer declines to deliver a drug at the 340B price over concerns that the drug is being diverted to non-patients in violation of federal law. (*Id.* at 15). Under these circumstances, the drug manufacturer is relying on *federal* law as a reason for not delivering a drug at the 340B price. (*Id.*) At the same time, this action would be a violation of the No-Restrictions Provision of S.B. 325. Consequently, a state actor must then determine if the person prevented from obtaining the drug was a "patient" as described by federal law. (*Id.* (citing 42 U.S.C. §§ 256b(a)(5)(B), 256b(d)(3)(A))). In other words, the state must determine whether

federal law required the drug to be sold at the 340B price to then determine if the drug was not "delivered" in accordance with state law. (*Id.*) Novartis contends that this scenario is why a statute like S.B. 325 is preempted because Congress, along with the Supreme Court in *Astra*, "have made clear that [HHS] alone makes those calls—not innumerable different state actors in 50 different states." (*Id.*)

Defendants do not attempt to refute the claim that the state may be called upon to interpret and apply federal law in the execution of S.B. 325. (*See* Case No. 2:24-cv-00272, ECF No. 28 at 23.) Given the structure of the statute, how could they argue otherwise? Instead, the state assures the Plaintiffs and the Court that "the potential for such interpretation and application within the limited context of such state law is minimal." (*Id.*) Without citing any law, state or federal, Defendants essentially say the state would adopt a "wait and see" approach. Building on Novartis's example of a diversion defense, which Defendants allege is a "rare case," the wait and see approach would entail the state being presented with a "timing and sequencing issue of how the state may proceed" in the face of a pending federal dispute resolution claim, resulting in an "issue of primary and secondary jurisdiction." Prelim. Inj. Hr'g Tr. (Case No. 2:24-cv-00272, ECF No. 53 at 74-75). Whether or not the state would actually have to wait for the federal process to play out first is, at best, unclear. (*See id.* at 75–76 ("[The Court]: So, you're saying the state would bring an enforcement mechanism, [and] because of a defense that was raised the state would step back and require the parties to go through the federal mechanism? [Defense Counsel]: It *may* have to. I mean, that's why I say it's a timing and a sequencing [issue].") (emphasis added).)

As yet another feature of S.B. 325, Defendants contend that a drug manufacturer may raise the argument that complying with federal law is an implied defense to S.B. 325. As Defendants

argued at the preliminary injunction hearing:

> [I]f diversion is taking place it doesn't impact the constitutionality of the state procedure. It may provide a defense for [a drug manufacturer] to say in some situation that . . . this isn't an otherwise qualifying 340B transaction and that this wouldn't be something that, as a predicate, would be subject to enforcement, but . . . the fact that the underlying 340B program is subject to abuse, fraud, whatever you want to call it, doesn't impact the viability of state law.

(*Id.* at 73–74.) Defendants cite no law within S.B. 325 or elsewhere that offers federal compliance as an affirmative defense to violating S.B. 325.[6]

Before addressing the constitutionality of the Enforcement Provisions directly, the Court pauses to address an underlying issue animating most of the parties' arguments—is S.B. 325 about regulating price or delivery? Supposedly in the face of Congressional silence on delivery of 340B drugs, creating non-conflicting delivery requirements would not violate the Supremacy Clause. *See, e.g., Sanofi Aventis U.S., LLC v. U.S. Department of Health and Human Services*, 58 F.4th 696, 703 (3d Cir. 2023). If, however, S.B. 325 is an attempt to enforce 340B's pricing scheme, then the statute would be preempted according to existing Supreme Court precedent. *See Astra*, 563 U.S. at 119–20. Given the outcome determinative nature of whether S.B. 325 is a price or delivery regulation, the parties disagree as to the statute's scope. For the reasons that follow, the Court finds that Plaintiffs' characterization that S.B. 325 regulates price, not delivery, is correct.

Defendants assert that S.B. 325 is about delivery, not price. They contend that the federal 340B Program has been found to be "silent about delivery." (Case No. 2:24-cv-00272, ECF No.

[6] Potentially, Defendants could be referring to the language in the No-Restrictions Provision that reads "unless the receipt of the 340B drug is prohibited by the United States Department of Health and Human Services." W. Va. Code § 60A-8-6a(b)(1). Defendants have not made this clear. However, even if this is the hook for such an affirmative defense, it is not enough to save S.B. 325 as will be explained later in this opinion.

28 at 21 (citing, e.g., *Sanofi Aventis U.S.*, 58 F.4th at 703).) In this void, Defendants claim that S.B. 325 only addresses delivery because the law "simply says that any participant in the 340B Program . . . cannot refuse delivery to 'a location authorized by' a Covered Entity, which may include the Covered Entity's internal locations . . . and also its external locations," such as contract pharmacies. (Case No. 2:24-cv-00271, ECF No. 33 at 23 (citing W. Va. Code § 60A-8-6a(b)(1)).)

That characterization, however, is unconvincing given that Defendants essentially have acknowledged the replenishment model as the controlling drug distribution model in West Virginia. *See supra* Part I.B. Because the drug is already in the hands of the contract pharmacy even before the patient arrives at the pharmacy, the question is not about delivery of the drug. The question is only about what price the pharmacy and the covered entity will pay the manufacturer for the replenished drug upon distribution of the 340B Program eligible one. Put another way, the system is about delivery *at a given price*, not delivery *per se*.

Price is what distinguishes between an "ordinary drug" and a 340B Program drug—a fact that seems to be reflected in the statute itself. *See* W. Va. Code § 60A-8-6a(a)(1) ("'340B drug' means a drug that . . . [h]as been subject to any offer for reduced prices by a manufacture under [the 340B Program]."). Novartis has established this fact in its briefing. It asserts that S.B. 325 "has a substantial impact on the types of transactions that trigger the 340B discount under federal law and the volume of discounts manufacturers must offer." (*See* Case No. 2:24-cv-00272, ECF No. 45 at 13 (citing Verified Compl. ¶¶ 35–37, 62).) That is because "Novartis's wholesalers and retailers already deliver Novartis's drug products to contract pharmacies throughout West Virginia," irrespective of the ceiling price it may charge. (*Id.*) Thus, a manufacturer risks violating S.B. 325 "not by withholding drugs from contract pharmacies, but by refusing the 340B

discount when delivering its drugs to those pharmacies." (*Id.*) None of the non-binding authority that Defendants cite as examples of similarly upheld statutes indicates that the replenishment model was considered by those respective courts.

In finding that S.B. 325 operates as a means to enforce the 340B ceiling price, the Court's preemption analysis is guided by binding Supreme Court precedent in *Astra*. There, a California county—which also operated as a 340B Program covered entity—attempted to utilize a theory of contract law to enforce the 340B Program. *Astra*, 563 U.S. at 116. The county, recognizing that it could not enforce the statute through a private right of action, claimed that it could sue on the issue of whether a drug was delivered at the 340B price based on the argument that it was deprived of contract benefits as a third-party beneficiary. *Id.* at 116–17.

The *Astra* Court rejected the county's argument. *Id.* at 121. Concluding that a "third-party suit to enforce an HHS-drug manufacturer agreement" was essentially "a suit to enforce the statute itself," the Court determined that the county impermissibly ventured into the federal government's enforcement of the 340B Program. *Id.* at 118–19. Adopting the United States Government's position, the Court recognized that "spreading the enforcement burden . . . is hardly what Congress contemplated when it 'centralized enforcement in the government.'" *Id.* at 119 (quoting Br. for United States as *Amicus Curiae* 32). An alternative ruling would not assist HHS. *Id.* at 120. Rather, "suits by 340B entities would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.* This would result in "a multitude of dispersed and uncoordinated lawsuits by 340B entities" and, "[w]ith HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial." *Id.* Congress chose alternative mechanisms in response to reports of "inadequate" 340B Program

enforcement, including a directive to "create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers." *Id.* at 121.

The fact that S.B. 325 seeks to enforce the 340B price matters because the state is essentially operating as the county in *Astra* did, only utilizing alternative enforcement mechanisms. In *Astra*, the county was attempting to argue, by utilizing contract-based litigation, that it was "overcharged" because the drug did not come to it at the 340B price. *Astra*, 563 U.S. at 116. The *Astra* Court rejected this as "a suit to enforce the statute itself," which Congress did not authorize. *Id.* at 118.

Similarly, Defendants attempt to enforce the 340B Program by penalizing those who "deny, restrict, or prohibit the acquisition of a 340B drug." *See* W. Va. Code §§ 60A-8-6a(b)(1), –(c)(1). A "340B drug," however, is just one that is a "covered outpatient drug within the meaning of [340B]; [h]as been subject to any offer for reduced prices by a manufacturer under [340B]; and [i]s purchased by a covered entity within the meaning of [340B]." W. Va. Code § 60A-8-6a(a)(1)(A)–(C). With the replenishment model as the operating system, the question is not whether the contract pharmacy will receive the 340B drug. Rather, it is what price—340B or otherwise—the manufacturer can charge.

Defendants attempt to refute this by saying that "whether or not the 340B price is being paid in a particular case isn't [part of the statute]." Prelim. Inj. Hr'g Tr. (Case No. 2:24-cv-00272, ECF No. 53 at 77.) When asked about what the state would do if there was a dispute about a drug delivered at a price other than the 340B ceiling, Defendants contended that "[w]hether or not this is an overcharge . . . has nothing to do with delivery." (*Id.*) Yet under the replenishment model the pharmacy will be delivered the drug regardless of its price. Only if the 340B drug—that is, if

the 340B price—is refused does the contract pharmacy have its "acquisition" of the drug restricted. Thus, an allegation of failing to charge the 340B price will result in the Enforcement Provisions coming to bear. Such a system is markedly similar to that of the one *Astra* rejected.

Even though *Astra*, unlike S.B. 325, related to preemption of private rights of action, the result is still the same. Federal schemes preempting both private action and state enforcement are nothing new. For example, the Employee Retirement Income Security Act of 1974 ("ERISA") provides a useful analog. Courts have held, consistent with the text of ERISA, that state laws which frustrate ERISA's "primary objective" of "provid[ing] a uniform regulatory regime over employee benefit plans" are preempted by the federal scheme. *Retail Industry Leaders Association v. Fielder*, 475 F.3d 180, 191 (4th Cir. 2007). Despite no statutory language prohibiting state based causes of action related to ERISA, the Supreme Court has held that certain private actions initiated by the public "would subject plans and plan sponsors to burdens not unlike those that Congress sought to foreclose through [ERISA's text]." *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 142 (1990). The Court further explained that, even if there was no inferred preemption of state-based private rights of action from ERISA's text, it would be implied because such private rights of action cut against the "exclusive remedy provided by [ERISA] . . . precisely the kind of special featur[e] that warrant[s] pre-emption." *Id.* at 144 (internal quotations omitted).

The Court can draw the same inference here. While the 340B Program creates implied preemption instead of express, and its preemption has so far only been addressed by bars to private actions operating as "suit[s] to enforce the statute itself," *Astra*, 563 U.S. at 118, the result comes out the same as in ERISA. After all, implied preemption still draws from the principle that

Congress intended to preempt state enforcement of the law. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996) ("[O]ur analysis of the scope of the statute's pre-emption is guided by our oft-repeated comment . . . that '[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case."). If private attempts to enforce the 340B Program go against "what Congress contemplated when it 'centralized enforcement in the government,'" *Astra*, 563 U.S. at 119, then so too would public attempts to enforce it. To put it bluntly, if West Virginia attempted to enforce 340B through litigation, *Astra* would directly prevent such a suit as an improper method of 340B enforcement. Why, then, does it matter if the chosen improper enforcement is litigation or legislation? The Court finds that it matters not. Consequently, even though *Astra* was specifically about private suits, its holding still controls here.

Price regulation is exclusively controlled by the federal statute, *see Astra*, 563 U.S. at 119–20, and state enforcement of it would necessarily intrude on the federal scheme. The *Astra* Court has already found that such attempts to enforce 340B are contrary to federal law. It is quite likely indeed that Plaintiffs will prevail on the merits given this binding Supreme Court precedent.

Another example of how S.B. 325 runs counter to *Astra*'s holding is the fact that differing state and federal adjudications may result because of the Enforcement Provisions. In rejecting covered entities' ability to essentially "enforce" the 340B Program, the Supreme Court in *Astra* cautioned that the alternative result would lead to a substantial "risk of conflicting adjudications" absent centralized enforcement. *Astra*, 563 U.S. at 120. As indicated above, Defendants do not disagree that the state would need to make some determinations of federal law. Instead, they contend that a claim of diversion, which would be adjudicated through the federal dispute resolution system, might operate as a defense to the state's enforcement. S.B. 325 does not

provide for this defense, however. Instead, it is likely that a drug manufacturer could both restrict distribution at the 340B price because of diversion concerns and be subject to sanction under S.B. 325. This risk of conflicting results cuts against Congress's vision of "centralized enforcement" that *Astra* found as necessary to execute the 340B Program. As it exists, the Enforcement Provisions present an obstacle to this centralized purpose.

As indicated above, Defendants argue that state actors would adopt a "wait and see" approach because of issues over "primary and secondary jurisdiction." The Court finds no comfort in these assurances. S.B. 325 offers no such guardrails, and the Court is unaware of any other law that would require such a result. Thus, the concern of HHS being unable to control the reins in the face of differing adjudications, as raised in *Astra*, seems particularly ripe in the face of S.B. 325. Plaintiffs are likely to demonstrate this at the merits stage.

The Court is aware out of circuit cases have addressed laws similar to the one at issue here. Yet these cases are distinguishable on a number of grounds. In rejecting a conflict preemption analysis for a Mississippi law, the district court in *AbbVie Inc. v. Fitch* cited the lack of "a clear purpose to preempt state laws" regarding drug delivery on the part of Congress. *AbbVie Inc. v. Fitch*, 2024 WL 3503965, *10 (S.D. Miss. July, 22, 2024). Yet in reaching that decision, the court did not discuss *Astra*'s potential impact on a conflict preemption analysis. Further, its treatment of that state law's enforcement provisions was brief and rather summarily concluded that Mississippi law "addresses delivery and Section 340B does not." *Id.* at *12. It was those reasons, and the plaintiffs' failures to meet their evidentiary burden on that particular motion for preliminary injunction, that resulted in the court's rejection. *Id.* at *15. Given that Plaintiffs have made a showing here that S.B. 325 would result in conflicting adjudications, and that the

enforcement mechanisms at issue here would conflict with *Astra*, the Court finds *Fitch* inapposite.

The Court similarly views the Eighth Circuit's decision in *Pharmaceutical Research and Manufacturers of America v. McClain*, 9 F.4th 1136 (8th Cir. 2024). In *McClain*, the court reviewed the denial of a preliminary injunction against an Arkansas law with features similar to S.B. 325. *Id.* at 1139–40. It rejected PhRMA's argument there because it "present[ed] no evidence of an obstacle." *Id.* at 1145. Instead, in a rather brief rejection of an obstacle preemption argument, the court concluded that the Arkansas law "does not require manufacturers to provide 340B pricing discounts to contract pharmacies" and, thus, presented "no obstacle for pharmaceutical manufacturers to comply with both [Arkansas law] and Section 340B." *Id.*

Again, the Court finds this case distinguishable. At minimum, Plaintiffs have demonstrated that the state would be called upon to determine certain federal questions in administering S.B. 325, a fact Defendants do not dispute. The concern for differing adjudications by differing sovereigns looms larger here than in *McClain*.

As one final attempt to avoid conflict preemption, Defendants point to S.B. 325's section (d), which states in pertinent part that "[n]othing in this section is to be construed or applied to be in conflict with . . . [a]pplicable federal law and related regulations." (Case No 2:24-cv-00272, ECF No. 28 at 20 (citing W. Va. Code § 60A-8-6a(d)(1)(A)).) This, Defendants argue, means "any discussion of SB 325's interpretation and application is conditioned on the intent to be construed and applied in any possible manner that avoids conflicting with federal law, including the 340B statute." (*Id.*) In response, Plaintiffs argue that savings clauses such as S.B. 325's have been found to "not bar the ordinary working of conflict pre-emption principles." (Case No. 2:24-cv-00272, ECF No. 45 at 12 (citing *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869

(2000)).) The Court agrees with Plaintiffs' assertion. After all, the Supreme Court has "repeatedly 'decline[d] to give broad effect to saving clauses where doing so would upset the careful regulatory scheme established by federal law.'" *Geier*, 529 U.S. at 870 (citations omitted). The Enforcement Provisions are poised to upset such a scheme, not least by potentially leading to conflicting adjudications.[7]

The Enforcement Provisions, much like the county in *Astra*, operate as a means of "enforcing the [340B] statute." *Astra*, 563 U.S. at 118. The fact that executing those provisions also runs the risk of producing conflicting adjudications further demonstrates what should be apparent—the Enforcement Provisions cut against the Supreme Court's holding in *Astra*. That binding precedent dictates the outcome of this case. For these reasons, the Court **FINDS** that the Plaintiffs are likely to show preemption of the Enforcement Provisions as well.

iii. The Remainder of S.B. 325

As indicated above, Plaintiffs are likely to succeed on the merits that the No-Audits and Enforcement Provisions are preempted by federal law and, thus, unconstitutional. As for the remainder of the statute, including the No-Restrictions Provision, Plaintiffs submit a host of arguments of various, and at times dubious, merit ranging from an unconstitutional taking to a

[7] The same could be said of the internal "savings clauses" within the No-Audits and No-Restrictions Provisions themselves. The No-Audits Provision holds that the prohibition on conditioning distribution on claims and utilization data is controlling "unless the claims or utilization data sharing is required by the United States Department of Health and Human Services." W. Va. Code § 60A-8-6a(b)(2). Similarly, the No-Restrictions Provision provides that the direct or indirect restriction on the "acquisition of a 340B drug" is prohibited "unless the receipt of the 340B drug is prohibited by the United States Department of Health and Human Services." W. Va. Code § 60A-8-6a(b)(1). Neither of these savings clauses do enough to overcome the obstacle S.B. 325 erects to achieving the federal purposes of the 340B Program. S.B. 325 still upsets the carefully crafted regulatory scheme of Congress even with these savings clauses. Further, even if the savings clause language in the No-Restrictions Provision is the supposed hook for a "federal affirmative defense" that Defendants allude to, it still does nothing to address the fact that S.B. 325 operates as a mechanism of federal enforcement. Consequently, these clauses within the No-Audits and No-Restriction Provisions cannot save S.B. 325 from preemption.

violation of copyright law. However, given the Court's finding on the preemption of the other two provisions of the statute, a far simpler rationale for enjoining the rest of S.B. 325 emerges. Namely, the remaining provisions are non-severable from the rest of the statute.[8]

"After finding an application or portion of a statute unconstitutional, [the Court] must next ask: Would the legislature have preferred what is left of its statute to no statute at all?" *Ayotte v. Planned Parenthood of Northern New England*, 546 U.S. 320, 330 (2006). "The question of the severability of a state statute's provisions is governed by state law." *Sons of Confederate Veterans, Inc. v. Commissioner of the Virginia Department of Motor Vehicles*, 288 F.3d 610, 627 (4th Cir. 2002).

While S.B. 325 contains no severability clause itself, Chapter 60A of the West Virginia code, where S.B. 325 is codified, has a general severability clause. *See* W. Va. Code § 60A-6-605 ("If any provision of this chapter or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act, and to this end the provisions of this act are hereby declared to be severable."). The Supreme Court of Appeals of West Virginia, when conducting severability analysis, has stated the following:

> A statute may contain constitutional and unconstitutional provisions which may be perfectly distinct and separable so that some may stand and the others will fall; and if, when the unconstitutional portion of the statute is rejected, the remaining portion reflects the legislative will, is complete in itself, is capable of being executed independently of the rejected portion, and in all other respects is valid, such remaining portion will be upheld and sustained.

State v. Tennant, 229 W. Va. 630, 642 (2012) (citation omitted). Further, the *Tennant* Court also noted that "[t]he most critical aspect of severability analysis involves the degree of dependency of statutes." *Id.* Thus, if "the valid and the invalid provisions of a statute are so connected and

[8] While the parties do not specifically address severability, the Court feels constrained to do so.

interdependent in subject matter, meaning, or purpose as to preclude the belief, presumption or conclusion that the Legislature would have passed the one without the other, the whole statute will be declared invalid." *Id.* (citations omitted).

Interdependence is clear here. Without the Enforcement Provisions, the No-Restrictions Provision has essentially no operation because it depends on the former to be executed. *See* W. Va. Code § 60A-8-6a(c) (explaining that "[t]he commission of any act prohibited by subsection (b)" constitutes a violation under the Enforcement Provisions). The Fourth Circuit has held that if a law "'can[] be enforced without' the challenged provision," then the non-challenged provisions can avoid the preliminary injunction. *North Carolina State Conference of NAACP v. McCrory*, 831 F.3d 204, 239 (4th Cir. 2016). The opposite is true for S.B. 325. The No-Restrictions Provision cannot be enforced without the Enforcement Provisions. The remaining sections of S.B. 325 also only serve as definitions and interpretive provisions. Therefore, Plaintiffs are entitled to the relief they request. Given the interdependent nature of the remaining provisions of S.B. 325, the whole of the law should be preliminarily enjoined.

iv. Likelihood of Success on the Merits and a Facial Challenge

Defendants finally argue that Plaintiffs are not likely to succeed on the merits because they will be incapable of meeting the "very high bar" of a non-First Amendment facial challenge. (Case No. 2:24-cv-00271, ECF No. 33 at 17.) This burden holds that "a plaintiff cannot succeed on a facial challenge unless he establishes that no set of circumstances exists under which the law could be valid, or he shows that the law lacks a plainly legitimate sweep." (*Id.* (citing *Moody v. NetChoice, LLC*, 144 S. Ct. 2383, 2397 (2024)).) PhRMA responds by asserting: 1) its "preemption challenge is not purely facial"; and 2) even if the Court does hold that this is a facial

challenge, a no set of circumstances test "would make no sense" for obstacle preemption purposes. (Case No. 2:24-cv-00271, ECF No. 47 at 16–17.)

Ultimately, Plaintiffs have raised a facial challenge to S.B. 325. The Plaintiffs seek a final disposition of this case by granting their prayer for relief and the issuance of "an order and judgment declaring that SB 325 is unconstitutional and violates federal law." (Case No. 2:24-cv-00271, ECF No. 1 at 47.) This, however, does not undermine the rationale for issuing a preliminary injunction. Other courts have aptly pointed out that applying the facial challenges standard to conflict preempted statutes makes little sense. *See Lozano v. City of Hazleton*, 724 F.3d 297, 313 ("That approach would reject a conflict preemption claim in a facial challenge whenever a defendant can conjure up just one hypothetical factual scenario in which implementation of the state law would not directly interfere with federal law."). Here, too, it makes little sense to say the Plaintiffs—who are drug manufacturers—have failed to demonstrate that there are no circumstances where a law targeting drug manufacturers can be legitimately applied. Swap in any of PhRMA's, or Novartis's, or AbbVie's peers and the result is the same—the law is still an obstacle to the federal scheme. If S.B. 325 is an obstacle preempted by federal law, it will be an obstacle preempted no matter who the plaintiff is.

B. Factor Two: Plaintiffs Will Suffer Irreparable Harm in the Absence of Preliminary Relief

Having met their burden under the first factor of *Winter*, Plaintiffs next must sufficiently demonstrate that they will suffer irreparable harm absent a preliminary injunction. To that end, each Plaintiff takes a slightly different tack. Novartis argues that it faces a "Hobson's choice: risk draconian penalties, or comply with an unconstitutional law." (Case No. 2:24-cv-00272, ECF No. 7 at 32.) Either outcome, it argues, leads to irreparable harm. (*Id.*) It asserts that enduring

"an unconstitutional state enforcement action" satisfies the second factor because "loss of constitutional rights constitutes irreparable harm for preliminary-injunction purposes." (*Id.* collecting out of circuit cases).) Further, Novartis argues that failing to comply "comes with severe penalties, including a "$50,000 per violation [penalty]," among the various other sanctions faced by drug manufacturers under S.B. 325. (*Id.*) As supported by its declarations, "Novartis relies on the revenues generated from the sales of its drugs to recoup the high costs of developing those drugs," and the Enforcement Provisions' sanctions "would drain Novartis's ability to commit to the same level of investment in the research and development programs" it maintains. (*Id.* at 33 (citing Declaration of Odalys Caprisecca, (ECF No. 6-1 at ¶¶ 12–14)).) Should Novartis opt to comply, it claims it will cause "unrecoverable financial losses." (*Id.*) That is because [o]nce the 340B discounts are made, there is no readily apparent mechanism for Novartis to recover them from the contract pharmacies or covered entities—under either federal or state law." (*Id.*) Novartis concludes, "[t]he ADR process provides no obvious path for [it] to recoup a 340B discount provided on account of a state law mandate later found to be invalid. And the state law provides for no such mechanism either." (*Id.*)

PhRMA echoes these points as well. It argues that, among other things, their members would "suffer irreparable harm in the form of unrecoverable compliance costs and unrecoverable lost resources . . . or face West Virginia's imposition of draconian civil penalties." (Case No. 2:24-cv-00272, ECF No. 21 at 35.) On the one hand, PhRMA suggests that its members "will be required to continue to devote funds and resources to ensuring compliance with S.B. 325 and will likely, in some cases, be required to retain outside assistance by contracting with a company to help ensure compliance with the law." (*Id.* at 36.) These "costs are unrecoverable given West

Virginia's sovereign immunity." Like Novartis, PhRMA also notes its members will face severe fines if it fails to comply, (*Id.*) AbbVie also takes note of these fines, but describes them as "unconstitutionally excessive." (Case No. 2:24-cv-00298, ECF No. 8 at 23.)

Defendants do little to contest the existence of irreparable harm. What little resistance they do put up can be summarized as follows: "Arguing that the equities favor an injunction, Plaintiff focuses on its pecuniary interest, harkening back to its alleged irreparable harm. . . . This gives short shrift to the concerns of West Virginia residents and entities that will be deprived of positive repercussions of SB 325." (Case No. 2:24-cv-00272, ECF No. 28 at 26 (internal citation omitted).) Ironically, Defendants themselves seem to have given "short shrift" to discussing the second *Winter* factor.

Nevertheless, the Plaintiffs bear the burden of proving each factor by a clear showing. *See Imagine Medispa*, 999 F. Supp. 2d at 868. It does not appear that a violation of the Supremacy Clause, standing alone, is sufficient to *per se* qualify as irreparable harm. *See Association of American Publishers, Inc. v. Frosh*, 586 F. Supp. 3d 379, 394 (D. Md. 2022) (recognizing that, while Fourth Circuit precedent has found *per se* irreparable harm for "loss of constitutional freedoms guaranteed by the Bill of Rights," it has "not [held] that a violation of the Supremacy Clause gives rise to irreparable harm *per se*."). However, being subjected to fines and being forced to spend resources on compliance with a law ultimately struck down has been sufficient to meet irreparable harm. *See Air Evac EMS v. Dodrill*, 548 F. Supp. 3d 580, 594–95 (S.D. W. Va. 2021) (Johnston, J.) (recognizing irreparable harm where a plaintiff "may be subject to fines; forced to spend time, money, and resources to comply with the new requirements and regulations under [a law] that may later be struck down, or may ultimately be forced to close its doors

entirely").

There is a clear showing that enforcement would lead to such harms. The text of the Enforcement Provisions alone "subject a violator to $50,000 per each violation," and violations accrue for "[e]ach package of 340B drugs determined to be subject to a prohibited act." W. Va. Code §§ 60A-8-6a(c)–(1)(A), –(2). Plaintiffs and their members may very well be required to contend with and defend against potential investigations pursued by the Attorney General and the Board of Pharmacy. W. Va. Code §§ 60A-8-6a(c)–(1)(A), –(3)(A). Further, Defendants will be subjected to compliance costs associated with whatever rules the Board of Pharmacy decides to create under this newfound authority. All of these rather severe consequences flow from the effect of a law that this Court finds likely to be preempted and thus unconstitutional.

These harms are more than speculative. In fact, as mentioned in the status conference preceding this order, Defendants acknowledge that there are already a growing number of complaints pending before the Board of Pharmacy following the enactment of S.B. 325. Such complaints indicate that enforcement of S.B. 325 is imminent,[9] supplying a justification for issuing an injunction. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 382 (1992) ("In suits such as this one, which the plaintiff intends as a 'first strike' to prevent a State from initiating a suit of its own, the prospect of state suit must be imminent, for it is the prospect of that suit which supplies the necessary irreparable injury."). Given the likelihood of harm absent a preliminary injunction, Plaintiffs have sufficiently met their burden under the second *Winter* factor.

[9] Just before the Court entered this order, Defendants advised that Board of Pharmacy began processing complaints under S.B. 325. (*See* 2:24-cv-00272, ECF No. 62.)

C. Factors Three and Four: the Balance of Equities Tips in Plaintiffs' Favor; a Preliminary Injunction is in the Public Interest

Finally, the last two *Winter* factors tip in Plaintiffs' favor. *Winter* factors three and four merge when the government is a defendant. *See Pierce v. North Carolina State Board of Elections*, 97 F.4th 194, 225 (4th Cir. 2024) ("Plaintiffs must show 'that the balance of equities tips in [their] favor' [*Winter* factor three] and 'that an injunction is in the public interest.' [*Winter* factor four] . . . These 'factors merge when the Government is the opposing party.'") (citations omitted). AbbVie argues that the "'balance of the equities favors preliminary relief' when the 'issuance of a preliminary injunction . . . prevents the state from enforcing restrictions' that are likely to be held invalid." (Case No. 2:24-cv-00298, ECF No. 7 at 34 (citing *Leaders of a Beautiful Struggle v. Baltimore Police Department*, 2 F.4th 330, 346 (4th Cir. 2021)).) Rather, granting an injunction serves "'the primary purpose of' temporary injunctive relief: to 'preserve the object of the controversy in its then existing condition—to preserve the status quo.'" (*Id.* (citing *Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014)).) On the other hand, the public interest is served by "seeing that federal law is enforced and not countenancing state efforts to reset the metes and bounds of participation in federal healthcare programs." (*Id.* at 35. citations omitted).)

Defendants counter that the "public also has a substantial interest in seeing the statutes lawfully adopted by their democratically-elected Legislature enforced." (Case No. 2:24-cv-00272, ECF No. 28 at 26.) They argue that the public will be served by denying the injunction because allowing the statute to be enforced would lead to "increased distribution of and improved access to 340B drugs" and would benefit "West Virginia's widespread rural population that qualifies for 340B patient status." (Case No. 2:24-cv-00272, ECF No. 28 at 26.)

This, of course, misses the point of the 340B Program. After all, 340B drug pricing is for the benefit of the *covered entities*. They enjoy the benefits of the 340B Program, *not patients themselves*, as acknowledged by all parties. Further, no matter how the state pursues even laudable policy goals, it still must not violate the Supremacy Clause. If the chosen scheme runs afoul of the Constitution, it is invalid. Enforcing an otherwise preempted statute at minimum harms the Plaintiffs, especially when such burdensome penalties and compliance costs are at stake.

This injunction does not grant drug manufacturers a blank check. Should PhRMA's members, Novartis, or AbbVie engage in conduct that fails to adhere to their obligations under the 340B Program, such as overcharging covered entities, HHS retains its power to enforce under its authority granted by Congress. *See Astra*, 563 U.S. at 120. A preliminary injunction does nothing to upset the federal program. However, the enforcement of S.B. 325 likely would. Complying with S.B. 325 means that drugs may be improperly diverted at the 340B price without any ability for the manufacturers to recoup the loss by utilizing the federal dispute resolution system. S.B. 325 also offers no recovery mechanism.

Thus, the interest in preserving the status quo is justified here. The *Winter* factors all favor Plaintiffs. Until the Court can make a final determination on the merits, a preliminary injunction keeps the parties in their respective conditions prior to S.B. 325's enactment.

D. CONCLUSION

For these reasons, Defendants' motion to dismiss in the PhRMA case, (Case No. 2:24-cv-00271 ECF No. 34), is **DENIED**. Plaintiffs' motions for a preliminary injunction, (Case No. 2:24-cv-00271, ECF No. 20), (Case No. 2:24-cv-00272, ECF No. 6), (Case No. 2:24-cv-00298, ECF No. 7.), are **GRANTED**. While these cases are pending, Defendants are enjoined from

enforcing West Virginia Code § 60A-8-6a against the Plaintiffs.

In light of the Court's findings regarding the absence of any meaningful harm to Defendants related to this injunction, as well as the likelihood that Plaintiffs will succeed on the merits, the Court **ORDERS** that the security required by Federal Rules of Civil Procedure 65(c) be set at **ZERO.** *See, e.g., Doe v. Pittsylvania*, 842 F. Supp. 2d 927, 937 (W.D. Va. 2012).

Because Defendants' motion is denied, Defendants are **ORDERED** to file an answer to PhRMA's complaint within fourteen days of this order pursuant to Federal Rules of Civil Procedure 12(a)(4)(A). (Case No. 2:24-cv-00271, ECF No. 1.)

IT IS SO ORDERED.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: December 17, 2024